

# Listing a Bulk Ingredient/Bulk Drug Product in SPL Format

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# Administrative (Document Tracking Information)

## Basic information to identify the SPL document:

- **Document ID:** is a Globally Unique Identifier (GUID) and is unique for each version of the document. Letters used in a GUID are lower case.
- **Document Type:** The `<code>` is the LOINC code which provides information on the document type.
- **Effective Time:** provides a date reference to the SPL version including the year, month and day as yyyyymmdd.
- **SetID:** is a GUID and is a unique identifier for the document that remains constant through all versions/revisions of the document.
- **Version number:** is an integer greater than zero that provides a sequence to the versions of the document.

# Document Type

- BULK INGREDIENT

# Listing Data

- **Drug Listing**
- **Labeler**
  - Name
  - DUNS Number
- **Establishment**
  - Name
  - DUNS number
  - Mark as Confidential
  - Type of operation

# Listing Data cont...

- **Product Information**
  - Proprietary Name
  - Proprietary Name Suffix
  - Non-Proprietary Name
  - NDC Product Code
  - Dosage Form
  - DEA Schedule (if applicable)
  - Route(s) of Administration
- **Active Ingredient**
  - Name(s)
  - Unique Ingredient Identifier(s) (UNII)
  - Strength

# Listing Data cont...

- **Active Moiety**
  - Name(s)
  - Unique Ingredient Identifier(s) (UNII)
  - Basis of Strength

# Listing Data cont...

- **Packaging**
- **As ordered**
- **No asterisks permitted**
  - **Immediate packaging**
    - NDC Package Code (10 digit)
    - Quantity
    - Package Type
  - **Outer package**
    - NDC Package Code (10 digit)
    - Quantity
    - Package Type

# Listing Data cont...

- **Marketing Date**
  - Product Status
  - Start Marketing Date
  - End Marketing Date (if applicable)
- **Marketing Category**
  - Marketing Category
  - Application or citation number
  - Application or citation number code system



# Labeler Information in Listing SPL

- Name
- DUNS number

# Listing a API w/Finished Dosage Form Product

- Inclusion of the establishment for the API in the SPL file for the finished dosage form product. This electronically lists the API.
- Importation of API
  - The NDC for the finished product could be used for import purposes.

# Drug Listing: Establishment Information for API Manufacturers

- Establishment information for manufacturers of your **active pharmaceutical ingredient (API)** used in your products
  - **Recommendation** that this information **should** be included in your **electronic drug listing document** (SPL file)

# **Product Data Elements**

# Product Data Elements

- Product
  - Product names
- Description
  - Ingredients
  - Strength
  - Dosage form
  - Route of administration
  - Controlled substance code
- How supplied
  - Packaged product

**Only terms in the controlled terminology are allowed.**

# Product Name and NDC Product Code

- The proprietary/trade and ingredient name data elements only include the name and do not include any additional qualifiers such as trademark symbols, route of administration, or dosage forms. (SPL R4 only: Suffix element may contain “XL” “ER”)
- The NDC product code in SPL documents is comprised of the first two segments of the NDC

**Proprietary name: “PROPRIETARY NAME”**

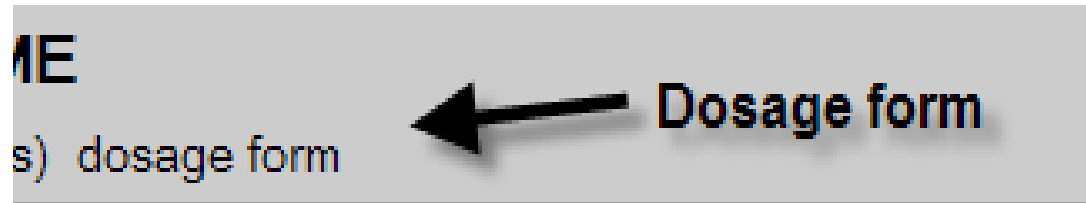
**Name of active ingredient: “name(s) of active ingredient(s)”**

**PROPRIETARY NAME**

name(s) of active ingredient(s) dosage form

# Dosage Form

- The dosage form is the name for the drug dosage form taken from the controlled terminology. Only terms in the controlled terminology are allowed.
- **APIs: POWDER OR LIQUID**



# Route of Administration

- Labeled route of administration is the name of the route of administration taken from the controlled terminology. Only terms in the controlled terminology are allowed. A product may have one or more route of administration.
- For APIs – NOT APPLICABLE



# Active Ingredient

- The active ingredient includes the active ingredient name and identifier (Unique Ingredient Identifier (UNII) , strength, and the active moiety names and identifier (UNII). All active ingredients have at least one active moiety (in some cases two active moieties). Names of active ingredient **should not include designations such as USP or NF**. The name is taken from controlled terminology. Only terms in the controlled terminology are allowed. For ingredients, the controlled terminology is found in the FDA Substance Registration System/Ingredient Dictionary (SRS/ID). The **UNII is linked to the name** of the ingredient.
- Active moieties - more than one active moiety can be included for each active ingredient.

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
name(s) of active ingredient(s) (name of active moiety number 1 and name of active moiety number 2)	name(s) of active ingredient(s)	50 mg

# Strength of Ingredient APIs

- SPL R4 documents will allow companies to **designate strength based on the active ingredient, active moiety.**

## Example

Numerator: **10 kg**

Denominator: **10 kg**

# Marketing Category

- Select the appropriate marketing category for the drug product.

Marketing Information	
Marketing Category	
NDA	

# Application or Citation Number Field

- There is no application or citation number for APIs

# Marketing Status & Date

- The marketing status describes the activity of the product
- The expiration date of the last lot released to the marketplace.

# Marketing Status & Dates

- Status of product
  - **Active:** on the market
  - **Completed:** when marketing is done the drug is no longer going to be available on the market.
  - Active or completed timestamp: effectiveTime value.
- Low value
  - Time on the market
  - Determines release of CoL/Listing SPL to public
- High value
  - Time off the market (e.g. the expiration date of the last lot released to the market.)

Marketing Start Date	Marketing End Date
01/24/2005	

# Common Errors in eList Pilot Program Submissions

- XML file sent not enclosed within a folder
- XML file name is not the document ID root name
- Spaces before telephone number
- Hyphens in DUNS number
- SPL file created with outdated SPL xforms
- Two-character country code used in place of three-character country code (ISO-3166 - <ftp://ftp1.nci.nih.gov/pub/cacore/EVS/FDA/SPL/>)

**QUESTIONS?**